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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO. <u>hak</u>
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09/160,133 09/25/98 LELEU

J	6-1032-021
EXAMINER	

HM22/0315

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ART UNIT	PAPER NUMBER
WHITE, L	6

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DATE MAILED:

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-6, 9 and 10 is/are rejected.
- ☒ Claim(s) 7 and 8 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Claims 7 and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

2. Claims 1-6 and 9 are objected to because of the following informalities: British spelling of terms is noted through out the claims. The English spellings of these terms is preferred. See the terms "crystallising" (all occurrences) and "crystallised" in claim 9 which should be changed to --crystallizing--- and ---crystallized---, respectively. Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3, 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The methods of claims 3 and 6 are seen to be unenabled. They are drawn to a method for making a crystalline maltitol composition, by a single step - crystalizing a maltitol syrup. See page 7, lines 21-25, wherein a reduced content of maltosyl-1,6-maltitol appears to be critical/necessary. Further required or missing steps for the process are seen on page 9, line 7 through page 14, line 16. Steps are clearly laid out in the specification but are not seen in the claims. No support for a single step process is seen in the instant specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, the phrase "characterised in that" should be changed to ---wherein--- in order to make the claim more definite.

In claim 1, line 2, the term "including" is seen to render claim 1 indefinite wherein it is difficult to ascertain if applicant intends for the bipryamidal form of the compound to "include" additional features or components. The terms "comprising" or "consisting" would be more favorable to particularly point out that which applicants intend as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 3 and 5-8 recite the broad recitation "maltitol content greater than or equal to 87%", and the claims also recites "preferably greater than or equal to 92%, and more preferentially greater than or equal to 96%" which is the narrower statement of the range/limitation.

In claims 2, 5, 7 and 9, line 2 of each claim, the term "characterised in that" should be changed to ---wherein--- in order to make the claims more definite.

In claims 3, 6 and 8, lines 2 and 3 of each claim, the term "characterised in that it consists in" should be changed to ---comprising--- in order to make the claims more definite.

In claim 4, lines 1 and 2, the term "characterised in that" should be changed to ---wherein--- in order to make the claim more definite.

In claim 9 what is meant by "directing the form"? Does Applicant intend: a method/process for determining bipyramidal or prismatic crystalline form in a crystalline maltitol composition by controlling the maltotriitol content of the maltitol syrup in the preparation of crystalline maltitol? The phrase "directing the form" is not clear which renders claim 9 indefinite.

7. Claim 10 provides for the use of maltotriitol to modify or control the form of maltitol crystals, but, since the claim does not set forth any steps involved in the method/process, it is unclear what methodological steps, reaction processes, reagents and reaction conditions applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kataura et al (European Patent No. 741140).

Applicants claim modified maltitol crystals which are bipyramide in form including two regular tetrahedrons juxtaposed by their square section base with sides of 50 to 500 μm approximately, thus constituting regular octahedrons with edge length of approximately 50 to 500 μm . It is noted on page 3, first paragraph of the specification that by controlling the maltotriitol content of the maltitol syrup, it was possible to direct the form of the maltitol crystals towards one or other of the forms or towards a mix of the two forms (bipyramidal or prismatic) when the maltitol syrup is subjected to a crystallization stage. See page 6, 4th paragraph of the instant specification wherein the crystalline maltitol composition is constituted by maltitol crystals of bipyramidal form when the maltotriitol content, by weight of dry matter, is less than 1%.

Kataura et al disclose the production of crystalline maltitol comprising catalytically hydrogenating a maltose syrup containing 81-90 wt.% of maltose and chromatographing the resulting sugar alcohol syrup on a column of cation-exchange resin to obtain a maltitol syrup whose solids can comprise 99.9 wt.% maltitol whereby the maltitol syrup may be concentrated and crystallized, and separating the crystalline maltitol from the mother liquor (see English language abstract). The instant claims differ from the Kataura et al reference by reciting that the maltitol crystals are of bipyramidal form. The maltitol syrup whose solids comprises 99.9 wt.% maltitol is within the scope of a maltitol crystal having a bipyramidal form since a 99.9 wt.% maltitol content suggests a maltotriitol content of less than 1%. One having ordinary skill in the

art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly.

12. Claims 4-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devos et al (US Patent No. 4,846,139).

Applicants claim modified maltitol crystals which are prismatic in form, ending in plane faces constituting a tetrahedron, and that they are 100 to 400 μm long and about 20 to 100 μm wide. It is noted on page 3, first paragraph of the specification that by controlling the maltotriitol content of the maltitol syrup, it was possible to direct the form of the maltitol crystals towards one or other of the forms or towards a mix of the two forms (bipyramidal or prismatic) when the maltitol syrup is subjected to a crystallization stage. See page 6, 5th paragraph of the instant specification wherein the crystalline maltitol composition is constituted by maltitol crystals of prismatic form when the maltotriitol content, by weight of dry matter, is greater than or equal to 4%.

Devos et al disclose crystalline maltitol and process for the preparation of crystalline maltitol. The process described by Devos et al enables maltitol syrups having a richness at least equal to 87% of maltitol and a maltotriitol content generally comprising between 2.5 and 13% by weight (see column 4, line 59 to column 5, line 7). See step (f) of claim 1 of the Devos et al patent wherein the process for the preparation of maltitol comprises crystallizing the maltitol from a concentrated fraction and providing maltitol crystals and mother-liquors, said maltitol crystals being separated from the mother-liquors. The instant claims differ from the Devos et al patent by reciting modified maltitol crystals as having a prismatic form. The maltitol syrup of the Devos et al patent comprising a maltotriitol content greater than 4% (see a maltotriitol content of 2.5% to 13% at column 5, line 7 of the Devos et al patent) suggests the preparation of maltitol crystals having prismatic form when the maltitol syrup is subjected to crystallization. One having ordinary skill in the art would have been motivated to employ the process of the prior art with the

expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly.

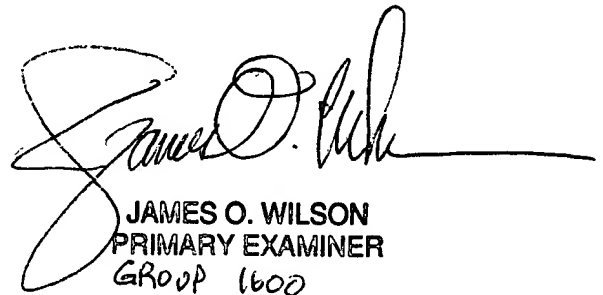
13. Summary: Claims 1-6, 9 and 10 are rejected; claims 7 and 8 are objected to.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the primary examiner signing this office action, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

White
March 8, 1999



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600